

# CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE

## INSPECTION SERVICES DIVISION

FOOD AND AGRICULTURAL CODE  
DIVISION 7, CHAPTER 4. LIVESTOCK DRUGS  
DIVISION 7, CHAPTER 4.5. LIVESTOCK: USE OF ANTIMICROBIAL DRUGS

AND

CALIFORNIA CODE OF REGULATIONS  
TITLE 3, DIVISION 5, CHAPTER 1. SALES OF RESTRICTED LIVESTOCK DRUGS  
TITLE 3, DIVISION 5, CHAPTER 2. SALES OF CALIFORNIA PRESCRIPTION DRUGS

### 2018 REVISIONS

#### CALIFORNIA CODE OF REGULATIONS, TITLE 3, DIVISION 5, CHAPTER 1 ADOPTED

Article 1 Section 5000 (a), (b), (c), (d), (e), (f)  
Article 2 Section 5001 (a), (b), (c), (d)  
Article 3 Section 5002 (a), (b), (c), (d), (e), (f)  
Section 5003 (a), (b), (c), (d), (e), (f)  
Article 4 Section 5004 (a), (b), (c)  
Article 5 Section 5005 (a), (b), (c), (d), (e), (f), (g), (h), (i), (j), (k)  
Section 5006 (a), (b), (c), (d)

#### CALIFORNIA CODE OF REGULATIONS, TITLE 3, DIVISION 5, CHAPTER 2 ADOPTED

Article 1 Section 5007 (a), (b), (c), (d), (e), (f), (g), (h), (i), (j)  
Article 2 Section 5008 (a), (b), (c), (d)  
Article 3 Section 5009 (a), (b), (c), (d)  
Section 5010 (a), (b), (c)  
Section 5011 (a), (b), (c), (d), (e), (f)  
Section 5012 (a), (b), (c)  
Section 5013 (a), (b), (c), (d), (e), (f)  
Article 4 Section 5014 (a), (b), (c), (d), (e), (f), (g), (h), (i), (j), (k), (l), (m), (n),  
(o)  
Section 5015 (a), (b), (c)

### 2015 REVISIONS

#### FOOD AND AGRICULTURAL CODE, DIVISION 7, CHAPTER 4.5 ENACTED

(No Article) Section 14400 (a), (b), (c)  
Section 14401  
Section 14402 (a), (b), (c), (d)  
Section 14403 (a), (b), (c)  
Section 14404 (a), (b), (c)  
Section 14405 (a), (b), (c), (d), (e), (f)  
Section 14406  
Section 14407  
Section 14408 (a), (b), (c), (d)

# TABLE OF CONTENTS

## FOOD AND AGRICULTURAL CODE

<b>CHAPTER 4. LIVESTOCK DRUGS [14200 – 14390]</b> .....	<b>1</b>
ARTICLE 1. LEGISLATIVE INTENT [SECTION 14200] .....	1
ARTICLE 1.5 DEFINITIONS [SECTIONS 14201 – 14209] .....	1
ARTICLE 2. GENERAL PROVISIONS [SECTIONS 14231 – 14233] .....	2
ARTICLE 3. EXEMPTIONS [SECTIONS 14261 – 14262] .....	2
ARTICLE 4. REGISTRATION [SECTIONS 14281 – 14296] .....	3
ARTICLE 5. RETAIL LICENSES FOR RESTRICTED DRUGS [SECTIONS 14321 – 14330] .....	5
ARTICLE 6. VIOLATIONS [SECTIONS 14351 – 14365] .....	6
ARTICLE 7. PENALTIES [SECTIONS 14381 – 14382] .....	8
ARTICLE 8. PROCEDURE FOR PROSECUTION [SECTION 14390] .....	9
<b>CHAPTER 4.5. LIVESTOCK: USE OF ANTIMICROBIAL DRUGS [14400 – 14408] ..</b>	<b>10</b>
Section 14400 .....	10
Section 14401 .....	10
Section 14402 .....	10
Section 14403 .....	10
Section 14404 .....	11
Section 14405 .....	11
Section 14406 .....	12
Section 14407 .....	12
Section 14408 .....	12

## CALIFORNIA CODE OF REGULATIONS

<b>CHAPTER 1. SALES OF RESTRICTED LIVESTOCK DRUGS .....</b>	<b>13</b>
ARTICLE 1. DEFINITIONS .....	13
§ 5000. Definitions .....	13
ARTICLE 2. GENERAL PROVISIONS .....	14
§ 5001. Sales of Restricted Livestock Drugs .....	14

ARTICLE 3. LICENSING.....	15
§ 5002. License Application.....	15
§ 5003. License Renewal. ....	16
ARTICLE 4. RECORDKEEPING .....	17
§ 5004. Sales Records. ....	17
ARTICLE 5. VIOLATIONS AND PENALTIES .....	18
§ 5005. Violations.....	18
§ 5006. Penalties.....	19
<b>CHAPTER 2. SALES OF CALIFORNIA PRESCRIPTION DRUGS .....</b>	<b>20</b>
ARTICLE 1. DEFINITIONS .....	20
§ 5007. Definitions.....	20
ARTICLE 2. GENERAL PROVISIONS .....	22
§ 5008. Sales of California Prescription Drugs.....	22
ARTICLE 3. ADDITIONAL REQUIREMENTS.....	22
§ 5009. Qualified Individuals.....	22
§ 5010. Sale Requirements. ....	24
§ 5011. Storage and Inventory Requirements.....	24
§ 5012. Written Operating Procedures.....	26
§ 5013. Pharmacist Oversight.....	26
ARTICLE 4. VIOLATIONS AND PENALTIES .....	27
§ 5014. Violations.....	27
§ 5015. Penalties.....	29

**FOOD AND AGRICULTURAL CODE**  
**DIVISION 7. AGRICULTURAL CHEMICALS, LIVESTOCK REMEDIES,**  
**AND COMMERCIAL FEEDS**  
**CHAPTER 4. LIVESTOCK DRUGS [14200 – 14390]**

**Article 1. Legislative Intent [Section 14200]**

**14200.** The Legislature hereby declares that this chapter, which prescribes the distribution and use of livestock drugs, is intended to assure that such drugs are available to livestock producers for their use in protecting the health of the livestock population of the state, and that such use will in turn benefit the general public by providing an abundant supply of wholesome food and fiber.

It is further declared that nothing in this chapter is intended to prevent a livestock producer from administering livestock drugs safely and effectively when such use is in accordance with the labeling directions for the drug used.

**Article 1.5 Definitions [Sections 14201 – 14209]**

**14201.** Unless the context otherwise requires, the definitions in this article govern the construction of this chapter.

**14202.** “Drug” means any of the following substances:

- (a) Any substance which is intended for use in the diagnosis, cure, mitigation, prevention, or treatment of disease.
- (b) Any substance, except food and water, which is intended to affect the structure or function of the body of any livestock.

**14203.** “Restricted drug” means any livestock drug which is sold in such form that it might be administered to humans and if so administered would be dangerous to the health of such humans or any livestock drug which if improperly administered to livestock is dangerous to the health of such livestock or to humans who consume products from such livestock. Restricted drugs include all of the following:

- (a) Arsenic compounds and preparations.
- (b) Diethylstilbestrol and other substances which have a hormonelike action.
- (c) Sulfanilamide or substitute sulfanilamides.
- (d) Antibiotic preparations.
- (e) Such other drugs and their preparations which the director determines are hazardous to the health of livestock or the public safety.

**14204.** “Label” includes written and graphic matter which is imprinted upon, or upon paper or other material affixed to, or accompanying, a container of a livestock drug.

**14205.** “Livestock” includes all animals, poultry, and bees, and aquatic and amphibian species which are raised, kept, or used for profit. It does not include those species which are usually kept as pets, such as dogs, cats, and pet birds.

**14206.** “Livestock drug” means any drug, combination of drugs, proprietary medicine, or combination of drugs and other ingredients which is prepared for administration to livestock orally, hypodermically, topically, or otherwise.

**14207.** “Manufacturer” includes any person that is responsible for the placing of a livestock drug on the market in this state.

**14208.** “Retailer” means any person that sells any livestock drug at retail.

**14209.** “Distribute” means to offer for sale, sell, exchange, or barter.

## **Article 2. General Provisions [Sections 14231 – 14233]**

**14231.** The director shall enforce this chapter and, in accordance with the provisions of Section 14200, may make and enforce such regulations which relate to the manufacture, sale, and use of livestock drugs as he may deem necessary to carry out this chapter.

**14232.** All money which is received under this chapter shall be paid into the Department of Agriculture Fund. Any money in the Department of Agriculture Fund which is derived under this chapter and Chapter 6 (commencing with Section 14901) of this division may be expended for the administration and enforcement of any of the provisions of such chapters, notwithstanding any other provision which limits the expenditure of any such money to the specific purposes or to the administration or enforcement of each of such chapters separately.

**14233.** The provisions of this chapter shall be controlling over those of any other provisions of law which are in conflict with them. No act or thing which is authorized or permitted by this chapter shall be in violation of any other provisions of law.

## **Article 3. Exemptions [Sections 14261 – 14262]**

**14261.** This chapter, except Section 14363, does not apply to any of the following:

(a) Any livestock drug which is sold exclusively to, and used exclusively by, or under the direction of, a licensed veterinarian, nor to any livestock drug which is compounded by a registered pharmacist upon the prescription of a licensed veterinarian.

(b) Any drug or other preparation which is dispensed or compounded by a registered pharmacist at the request of the purchaser if such drug or preparation is sold at retail.

(c) Any commercial feed which is subject to Chapter 6 (commencing with Section 14901) of this division, irrespective of the presence in such commercial feed of any ingredients which otherwise would constitute a livestock drug.

**14262.** This chapter also does not apply to any of the following:

(a) Any livestock drug that is intended for, and that is used solely for, laboratory or experimental purposes.

(b) Any substance that is intended for, and that is used primarily as a pesticide and that is registered as a pesticide under Chapter 2 (commencing with Section 12751).

(c) Any biological product that is manufactured under a license issued by the United States Department of Agriculture or the State Department of Health.

(d) Any drug that is required by federal law to be sold on prescription only.

#### **Article 4. Registration [Sections 14281 – 14296]**

**14281.** A person shall not sell any livestock drug in this state prior to receipt of a registration certificate pursuant to this chapter.

**14282.** The manufacturer of any livestock drug shall apply to the director for registration of the livestock drug.

**14283.** The application shall be in a form which is supplied by the director. It shall show all of the following:

(a) The name of the applicant and the address of his principal place of business.

(b) The name, brand, or trademark under which the livestock drug is to be sold.

(c) The minimum net contents of each size and type of container in which the livestock drug is to be sold at retail.

(d) The name of each active drug ingredient and the quantity or proportion of each such ingredient.

(e) A statement of each purpose for which the livestock drug is to be used.

(f) A statement of the form in which the livestock drug is to be administered, the method of administration, and, if the method of administration involves the use of any special device which is supplied with such drug, a description of such device.

(g) A statement of the amount and frequency of the dosage which is to be recommended.

(h) Such other information and data as the director may require.

**14284.** The application shall also contain a detailed description, or be accompanied by a copy, of the label of each type and size of container in which the livestock drug is sold at retail.

**14285.** The label shall contain all of the following:

(a) The name, brand, or trademark of the livestock drug.

(b) The name of the applicant and his principal address.

(c) The minimum net contents of the container.

(d) A statement of the disease or ailments of livestock which it is claimed that the livestock drug will alleviate or cure.

(e) Adequate instructions as to use and administration and adequate warnings against improper use and administration of the livestock drug, including adequate withdrawal periods and product disposal times to prevent any dangerous drug residues in products produced by livestock for human consumption.

(f) The name and amount of each active drug ingredient.

(g) A statement which clearly indicates that the product is not for human use.

(h) If the livestock drug is a restricted drug, the words “restricted drug, use only as directed” in conspicuous letters.

(i) Such other information as the director may require to ensure proper use to safeguard the health of animals and humans who consume products from such animals. **14286.** If it is proposed that any instructions for use, other than those on the label, shall accompany containers of the livestock drug which are sold at retail, a copy of such instructions shall accompany the application for registration of the livestock drug.

**14287.** The director shall examine and consider the application together with all material, data, and information which accompanies it.

**14288.** The director shall refuse to register a livestock drug if he finds any of the following is true of the drug:

- (a) It is of little or no value for the purpose for which it is intended to be used.
- (b) It is dangerous to the health of livestock if used in accordance with the instructions.
- (c) The instructions for use do not contain adequate warnings against use in those conditions, whether pathological or normal, under which its use may be dangerous to the health of livestock or humans who consume products from such livestock, or against unsafe dosage, unsafe duration of use, or unsafe methods of administration.
- (d) If the application and the accompanying material, data, and information do not comply with the requirements of this chapter or are insufficient to permit the director to make the determinations which are required by this section.

**14289.** If the livestock drug is a restricted drug, the director shall also refuse registration if he finds that the instructions for use do not contain adequate and satisfactory directions as to the methods of handling, caring for, holding, or otherwise managing the livestock to which the drug is administered so as to eliminate any danger to the health of any person who might consume food products which are derived from such livestock.

**14290.** The registration of a livestock drug includes all of the following:

- (a) Registration of the drug and its ingredients.
- (b) Registration of the label.
- (c) Registration of the instructions for use.
- (d) Registration of the special device, if any, for the administration of the livestock drug.

**14291.** (a) The fee for a two-year registration certificate for a livestock drug is one hundred eighty dollars (\$180). The certificate period shall commence beginning January 1 of each even-numbered year and expire on December 31 of the next odd-numbered year.

(b) The fee for a registration certificate submitted during an odd-numbered year shall be ninety dollars (\$90), and the certificate shall remain in effect until December 31 of that year.

(c) The fee shall accompany the application for registration. The fee is not refundable if the registration is refused.

**14292.** If registration is granted, the original fee covers the registration for the remainder of the then current calendar year in which registration is granted.

**14293.** The fee for application for renewal of registration is one hundred eighty dollars (\$180) for a two-year period. It is payable on or before January 31st of each year. If it is not so paid, a penalty of fifty dollars (\$50) shall be added to the fee.

**14294.** The director may quarantine and remove from sale any livestock drug which is not registered pursuant to this chapter or any livestock drug which does not conform in all respects with its registration.

**14295.** The director shall have access at all reasonable hours to all premises which are used in the manufacture, sale, or storage of any livestock drug, or where livestock drugs are mixed in feed for administering to livestock. He may take samples and make such other investigations as are necessary to carry out this chapter and the regulations which are adopted pursuant to it.

**14296.** The director may revoke the registration of any livestock drug if he finds, from representative samples, that the drug as offered for sale fails to conform to its registration. The director may allow reasonable tolerances within which such samples may vary from the registration.

#### **Article 5. Retail Licenses for Restricted Drugs [Sections 14321 – 14330]**

**14321.** A person shall not sell any restricted drug in this state at retail unless he holds a license to do so issued pursuant to this chapter.

**14322.** Any person may file with the director an application for a license pursuant to this chapter. The application shall be on a form which is supplied by the director and shall contain such information as he may require.

**14323.** The application shall be accompanied by an application fee of fifty dollars (\$50). The fee is not refundable if the license is refused.

**14324.** If the license is issued, the application fee covers the license for the remainder of the current calendar year in which it is issued.

**14325.** The fee for the renewal application for a license is fifty dollars (\$50) per year, payable on or before January 31 of each year. If the fee is not paid by that date, a penalty of fifty dollars (\$50) shall be added to the fee.

**14326.** A separate license is required for each place of business at which any restricted drug is kept for sale, and for each mobile unit in which any such drug is kept for sale.



**14327.** The director may make an examination of the facilities which are available to the applicant for the proper handling and storing of restricted drugs and may limit the kinds or classes of such drugs that may be sold under a license to those which the applicant is equipped properly to handle and store.

**14328.** Each holder of a license under this chapter shall keep a record, in the manner and form prescribed by the director, of each sale of a restricted drug by the licensee.

**14329.** The record required pursuant to Section 14328 shall include all of the following:

- (a) A statement of the kind and quantity of the restricted drug sold.
- (b) The date of sale.
- (c) The name and address of the purchaser.
- (d) The signature of the purchaser.
- (e) Any other information as the director may determine is reasonably necessary to carry out the provisions of this chapter.

**14330.** The director shall revoke a restricted drug license if he finds that the holder of such license has failed to keep the required record of sales of such drugs, or is not properly handling or storing such drugs.

#### **Article 6. Violations [Sections 14351 – 14365]**

**14351.** It is unlawful for any person to sell any livestock drug which is subject to any provision of this chapter unless the drug is registered pursuant to this chapter.

**14352.** It is unlawful for any registrant to sell any livestock drug which does not conform with its registration.

**14353.** It is unlawful for any person to administer any registered livestock drug to any human being.

**14354.** It is unlawful for any person to sell any restricted drug unless such person has a license issued pursuant to this chapter.

**14355.** It is unlawful for any person to use or administer any registered livestock drug except in accordance with the label instructions for use which are supplied by the registrant, including all warnings, withdrawal periods, and livestock product disposal times.

**14356.** It is unlawful for the holder of a restricted drug license to sell a restricted drug without requiring the purchaser of the restricted drug to sign his name and write his address in the record of such sales.

**14357.** It is unlawful for any person to refuse to permit the entry into and inspection of any premises wherein any livestock drug is manufactured or sold for the taking of samples of such drug.

**14358.** It is unlawful for any person to sell any livestock drug except in the container in which it is packaged by the manufacturer or distributor or to sell any such drug unless its package bears the label of the manufacturer or distributor.

**14359.** It is unlawful for any person to make any false or misleading representation which relates to any livestock drug, whether such representation is communicated orally, graphically, pictorially, or otherwise.

**14360.** It is unlawful for any livestock owner or his or her agent to sell or dispose of treated livestock or livestock products within the specified withdrawal period without first notifying the buyer that the livestock or products have been treated. The notification shall be in a form prescribed by the director.

**14361.** The director may seize and hold any livestock drug which he has reasonable cause to believe is in violation of the provisions of this chapter or the regulations adopted pursuant to it. The director shall continue to hold the livestock drug until such time as the requirements of this chapter have been complied with, at which time the lot shall be released. If the requirements of this chapter cannot be complied with, the director shall issue an order for disposal of the livestock drug, in a manner determined by him to protect the public health and safety and accomplish purposes of this chapter.

**14362.** It is unlawful for any person to manufacture, distribute, sell, or use any livestock drug without complying with the provisions of this chapter and the regulations which are adopted pursuant to it.

**14363.** (a) It is unlawful for any livestock owner or agent to sell or dispose of any livestock or livestock carcasses which within 48 hours after the buyer takes possession have drug residues in excess of allowable federal or state tolerances. In addition to any other penalties imposed by this chapter, any livestock owner or agent violating this section shall be liable to the buyer for an amount equal to three times the purchase price of any livestock or livestock carcasses with drug residues in excess of allowable federal or state tolerances so long as the liability does not conflict with the federal Packers and Stockyards Act, and shall be liable for a civil penalty of not more than one hundred dollars (\$100) for each head of livestock or livestock carcass disposed of or sold. In addition, the livestock owner or agent shall be liable for any attorney's fees.

(b) In addition to the penalties imposed by this chapter, the sale or disposition of any livestock or livestock carcass which, within 48 hours after the buyer takes possession, has drug residue in excess of allowable federal or state tolerances, is punishable by an administrative fine, levied by the director, in the amount of two hundred fifty dollars (\$250) per head for a second or subsequent violation within a 12-month period.

(c) In lieu of assessing the administrative fine, the director may authorize a violator to attend an educational program on livestock drug residue avoidance which has been approved by the director. The violator shall successfully complete the program and provide proof to the director within 90 days from the occurrence of the violation.

(d) This section does not affect any rights or obligations under any contract between a livestock owner or agent, buyer, or any other party.

(e) Any additional funds collected as administrative fines pursuant to this section shall be deposited in the General Fund.

**14364.** (a) It is unlawful to sell or dispose of a bob veal calf for the purposes of slaughter without first affixing to the animal a producer identification number approved by the director.

(b) For purposes of this chapter, "bob veal calf" means a bovine animal 21 days of age or less or weighing 150 pounds or less, or as specified in Food Safety Inspection Service regulations of the United States Department of Agriculture.

(c) Bob veal calves that are identified as provided in Division 10 (commencing with Section 20001) are exempt from this section.

**14365.** (a) It is unlawful to sell or dispose of a dairy cull cow without first affixing to the animal a producer identification number issued by the director.

(b) For purposes of this chapter, "cull cow" means a female bovine animal 21 days of age or more, which is sold or disposed of for the purpose of slaughter.

(c) Cull cows that are identified as provided in Division 10 (commencing with Section 20001) are exempt from this section.

#### **Article 7. Penalties [Sections 14381 – 14382]**

**14381.** A violation of this chapter or of any regulation which is adopted by the director pursuant to this chapter is an infraction punishable by a fine of not more than five hundred dollars (\$500) for the first violation. A second or subsequent violation of this chapter is a misdemeanor punishable by a fine of not less than one hundred dollars (\$100) and not more than one thousand dollars (\$1,000).

**14382.** (a) The director may, after a hearing, refuse to issue or renew, or may suspend or revoke a livestock drug registration or restricted drug license for any violation of this chapter or any regulation which is adopted pursuant thereto.

(b) Upon calling a hearing, the director shall serve notice personally or by mail to the licensee or registrant specifying the time and place of the hearing at least 10 days prior to the hearing. At the hearing, the director may do all of the following:

(1) Administer oaths and hear testimony.

(2) Issue subpoenas requiring the attendance of the licensee, registrant, or witnesses, together with books, records, memoranda, papers, and all other documents that may be pertinent to the case.

(3) Compel the disclosure of the licensee or registrant and any witness of all the facts known to him or her regarding the case. In no instance shall any employee of the Feed, Fertilizer, and Livestock Drugs Branch serve as the hearing officer in any case under this section.

(c) Any person deprived of a license or registration has the right to appeal this action to the director.

## **Article 8. Procedure for Prosecution [Section 14390]**

**14390.** In addition to the remedies provided in this chapter, the department may bring an action in superior court and such court shall have jurisdiction upon hearing and for cause shown, to grant a temporary or permanent injunction restraining any person from violating any provision of this chapter or the rules and regulations adopted under this chapter. Any proceeding under the provisions of this section shall conform to the requirements of Chapter 3 (commencing with Section 525) of Title 7 of Part 2 of the Code of Civil Procedure. The department shall not, however, be required to allege facts necessary to show or tending to show irreparable damage or loss. The court may require such acts or course of conduct as necessary to effectuate the purpose of this chapter.

**FOOD AND AGRICULTURAL CODE**  
**DIVISION 7. AGRICULTURAL CHEMICALS, LIVESTOCK REMEDIES,**  
**AND COMMERCIAL FEEDS**  
**CHAPTER 4.5. LIVESTOCK: USE OF ANTIMICROBIAL DRUGS [14400 – 14408]**

**14400.** For purposes of this chapter, the following definitions apply:

(a) “Medically important antimicrobial drug” means an antimicrobial drug listed in Appendix A of the federal Food and Drug Administration’s Guidance for Industry #152, including critically important, highly important, and important antimicrobial drugs, as that appendix may be amended.

(b) “Livestock” means all animals and poultry, including aquatic and amphibian species, that are raised, kept, or used for profit. Livestock does not include bees or those species that are usually kept as pets, such as dogs, cats, and pet birds.

(c) “Veterinary feed directive” has the same definition as in Section 558.3 of Title 21 of the Code of Federal Regulations.

**14401.** Beginning January 1, 2018, a medically important antimicrobial drug shall not be administered to livestock unless ordered by a licensed veterinarian through a prescription or veterinary feed directive, pursuant to a veterinarian-client-patient relationship that meets the requirements of Section 2032.1 of Title 16 of the California Code of Regulations.

**14402.** (a) Beginning January 1, 2018, a medically important antimicrobial drug may be used when, in the professional judgment of a licensed veterinarian, the medically important antimicrobial drug is any of the following:

- (1) Necessary to treat a disease or infection.
- (2) Necessary to control the spread of a disease or infection.
- (3) Necessary in relation to surgery or a medical procedure.

(b) A medically important antimicrobial drug may also be used when, in the professional judgment of a licensed veterinarian, it is needed for prophylaxis to address an elevated risk of contraction of a particular disease or infection.

(c) A person shall not administer a medically important antimicrobial drug to livestock solely for purposes of promoting weight gain or improving feed efficiency.

(d) Unless the administration is consistent with subdivision (a), a person shall not administer a medically important antimicrobial drug in a regular pattern.

**14403.** (a) Notwithstanding Sections 14401 and 14402 of this code and Article 15 (commencing with Section 4196) of Chapter 9 of Division 2 of the Business and Professions Code, medically important antimicrobial drugs may be sold by retailers licensed pursuant to Article 5 (commencing with Section 14321) of Chapter 4 of Division 7 with a prescription or veterinary feed directive from a licensed veterinarian.

(b) This section shall not be construed to invalidate the requirement to obtain a prescription or veterinary feed directive to administer a medically important antimicrobial drug as required by Section 14401.

(c) The department may promulgate regulations to implement this section.

**14404.** (a) The department, in consultation with the Veterinary Medical Board, the State Department of Public Health, universities, and cooperative extensions, shall develop antimicrobial stewardship guidelines and best management practices for veterinarians, as well as livestock owners and their employees who are involved with administering medically important antimicrobial drugs, on the proper use of medically important antimicrobial drugs for disease treatment, control, and prevention. The guidelines shall include scientifically validated practical alternatives to the use of medically important antimicrobial drugs, including, but not limited to, the introduction of effective vaccines and good hygiene and management practices.

(b) The department shall consult with livestock producers, licensed veterinarians, and any other relevant stakeholders on ensuring livestock timely access to treatment for producers in rural areas with limited access to veterinary care.

(c) For purposes of this section, “antimicrobial stewardship” is a commitment to do all of the following:

(1) To use medically important antimicrobial drugs only when necessary to treat, control, and, in some cases, prevent, disease.

(2) To select the appropriate medically important antimicrobial drug and the appropriate dose, duration, and route of administration.

(3) To use medically important antimicrobial drugs for the shortest duration necessary and to administer them to the fewest animals necessary.

**14405.** (a) It is the intent of the Legislature that the department coordinate with the United States Department of Agriculture, the federal Food and Drug Administration, and the federal Centers for Disease Control and Prevention to implement the expanded antimicrobial resistance surveillance efforts included in the National Action Plan for Combating Antibiotic-Resistant Bacteria, and that the information gathered through this effort will help lead to a better understanding of the links between antimicrobial use patterns in livestock and the development of antimicrobial resistant bacterial infections.

(b) (1) The department shall gather information on medically important antimicrobial drug sales and usage, as well as antimicrobial resistant bacteria and livestock management practice data. Monitoring efforts shall not be duplicative of the National Animal Health Monitoring System and the National Antimicrobial Resistance Monitoring System, and, to the extent feasible, the department shall coordinate with the United States Department of Agriculture, the federal Centers for Disease Control and Prevention, and the federal Food and Drug Administration in the development of these efforts.

(2) In coordinating with the National Animal Health Monitoring System and the National Antimicrobial Resistant Monitoring System, the department shall gather representative samples from all of the following:

(A) California’s major livestock segments.

(B) Regions with considerable livestock production.

(C) Representative segments of the food production chain.

(c) The department shall work with willing participants to gather samples and shall consult with, and conduct outreach to, livestock producers, licensed veterinarians, and any other relevant stakeholders on the implementation of the monitoring efforts.

Participation in this effort shall be done in a manner that does not breach veterinary-client-patient confidentiality laws.

(d) (1) The department shall report to the Legislature by January 1, 2019, the results of its outreach activities and monitoring efforts. The department shall advise the Legislature as to whether or not participation is sufficient to provide statistically relevant data. The report shall be submitted in compliance with Section 9795 of the Government Code.

(2) This subdivision is inoperative on January 1, 2023, pursuant to Section 10231.5 of the Government Code.

(e) The department shall seek funds from federal, state, and other sources to implement this section.

(f) The department may promulgate regulations to implement this section.

**14406.** The department has the authority to request and receive copies of veterinary feed directives from the livestock owner, veterinarian, or distributor to fully implement the provisions of this chapter.

**14407.** Notwithstanding the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code), any information provided pursuant to this chapter and Section 14902.5, if that section is added by Senate Bill 770 of the 2015–16 Regular Session of the Legislature, shall be held confidential, and shall not be disclosed to any person or governmental agency, other than the department or the Veterinary Medical Board, for the purposes of enforcing the Veterinary Medicine Practice Act (Chapter 11 (commencing with Section 4800) of Division 2 of the Business and Professions Code), unless the data is aggregated to prevent the identification of an individual farm or business. Information may be shared with federal agencies so long as it is protected by the federal Confidential Information Protection and Statistical Efficiency Act of 2002 (Public Law 107-347).

**14408.** (a) A person who violates this chapter shall be liable for a civil penalty of not more than two hundred and fifty dollars (\$250) for each day a violation occurs.

(b) (1) For a second or subsequent violation, a person who violates this chapter shall be punishable by an administrative fine, levied by the secretary, in the amount of five hundred dollars (\$500) for each day a violation occurs.

(2) In addition to the administrative fine, the violator shall attend an educational program on the judicious use of medically important antimicrobial drugs that has been approved by the secretary. The violator shall successfully complete the program and provide proof to the secretary within 90 days from the occurrence of the violation.

(c) Subdivisions (a) and (b) do not apply to licensed veterinarians. If the Veterinary Medical Board determines that a veterinarian is in violation of the Veterinary Medicine Practice Act (Chapter 11 (commencing with Section 4800) of Division 2 of the Business and Professions Code), the veterinarian may be subject to disciplinary sanctions pursuant to the act.

(d) The moneys collected pursuant to this article shall be deposited into the Department of Food and Agriculture Fund and shall be available for expenditure upon appropriation by the Legislature.

**TITLE 3. CALIFORNIA CODE OF REGULATIONS**  
**DIVISION 5. LIVESTOCK DRUGS**  
**CHAPTER 1. SALES OF RESTRICTED LIVESTOCK DRUGS**  
**SECTIONS 5000 THROUGH 5006**

**ARTICLE 1. DEFINITIONS**

**§ 5000. Definitions.**

For purposes of this chapter, the following definitions apply:

(a) “Company representative” means an individual representing a restricted livestock drug licensee that is assigned to perform the duties required to maintain a restricted livestock drug licensee’s compliance with California livestock drug laws and regulations.

(b) “Livestock” includes all animals, poultry, and bees, and aquatic and amphibian species which are raised, kept, or used for profit. It does not include those species which are usually kept as pets, such as dogs, cats, and pet birds. “Species which are raised, kept, or used for profit” means:

(1) Livestock that are used for financial gain, commercial use, breeding, competition, or show; or

(2) Livestock whose owners are engaged in business using animals for financial gain, commercial use, breeding, competition, or show.

(c) “Parent company” means the legal business entity that owns a restricted livestock drug licensee.

(d) “Qualified individual” means a person who meets the requirements of Section 5009 of Title 3 of the California Code of Regulations.

(e) “Restricted livestock drug” means any livestock drug which is sold in such form that it might be administered to humans and if so administered would be dangerous to the health of such humans or any livestock drug which if improperly administered to livestock is dangerous to the health of such livestock or to humans who consume products from such livestock. Restricted drugs include all of the following:

(1) Arsenic compounds and preparations;

(2) Diethylstilbestrol and other substances which have a hormonelike action;

(3) Sulfanilamide or substitute sulfanilamides;



(4) Antibiotic preparations, including those medically important antimicrobial drugs federally labeled for over the counter sale listed in Appendix A of the federal Food and Drug Administration's Guidance for Industry #152, including critically important, highly important, and important antimicrobial drugs, as that appendix may be amended;

(5) Type A Medicated Articles as defined in Section 558.3(b)(2) of Title 21 of the Code of Federal Regulations (8/24/2016), which is hereby incorporated by reference; and

(6) Any drug that has a withdrawal period.

(f) "Restricted livestock drug licensee" is a location licensed pursuant to Article 3 of Chapter 1 of Division 5 of Title 3 of the California Code of Regulations where sales of restricted livestock drugs occur.

Note: Authority Cited: Sections 407 and 14231, Food and Agricultural Code. Reference: Sections 14203, 14205 and 14321, Food and Agricultural Code.

## **ARTICLE 2. GENERAL PROVISIONS**

### **§ 5001. Sales of Restricted Livestock Drugs.**

(a) A restricted livestock drug shall only be sold at retail within or into this state by a restricted livestock drug licensee. This includes:

(1) In-person sales at a physical place of business, including mobile units, and

(2) All sales conducted using the internet, electronic mail, telephone, facsimile, mail order, or catalog.

(b) A business located outside of the State of California that makes any retail sale of a restricted livestock drug into this state shall obtain a restricted livestock drug license prior to any such sale.

(c) A separate restricted livestock drug license is required for each place of business at which any restricted livestock drug is kept for sale, and for each mobile unit in which any such drug is kept for sale.

(d) All livestock drugs sold by restricted livestock drug licensees must be registered pursuant to Section 14281 of the Food and Agricultural Code.

Note: Authority Cited: Sections 407 and 14231, Food and Agricultural Code. Reference: Sections 14281, 14321 and 14326, Food and Agricultural Code.

### **ARTICLE 3. LICENSING**

#### **§ 5002. License Application.**

(a) The restricted livestock drug license application required pursuant to Section 14322 of the Food and Agricultural Code shall contain:

(1) The following information for the parent company:

(A) The legal business name, Federal Tax ID number, and telephone number.

(B) The full legal name of the owner or owners.

(C) The mailing address, including street number, city, county, state, and ZIP code.

(D) The company representative who shall be responsible for compliance with the livestock drug laws and regulations. This person shall serve as the Department's primary point of contact for the parent company. The following information shall be provided for the company representative: full legal name, title, email address, and telephone number.

(E) The type of entity (corporation, partnership, sole proprietorship, limited liability company, co-partnership, or other). If other, the type shall be specified.

(2) The following information for the location to be licensed:

(A) The physical location where the sale of restricted livestock drugs will occur, including street number, city, county, state, and ZIP code.

(B) Whether the location to be licensed conducts online sales. If the location to be licensed conducts online sales, the website where sales are conducted shall be provided.

(C) The manager for the location to be licensed. This person shall serve as the Department's primary point of contact for the location to be licensed. The following information shall be provided for the manager: full legal name, title, email address, and telephone number.

(D) Whether the location to be licensed is a mobile unit. If the location to be licensed is a mobile unit, the license plate number shall be provided.

(E) Whether the location to be licensed conducts sales of restricted livestock drugs to other businesses for the purpose of resale.

(F) Whether the business to be licensed intends to sell California prescription drugs as defined in Section 5007(a) of Title 3 of the California Code of

Regulations. Retailers that indicate such intent shall comply with all requirements of Chapter 2 of Division 5 of Title 3 of the California Code of Regulations and shall submit all of the following:

1. The full legal name of each qualified individual that will sell California prescription drugs and documentation that each individual identified meets the requirements of Section 5009 of Title 3 of the California Code of Regulations.
  2. Either a written certification from a consulting pharmacist pursuant to Section 5013(b) of Title 3 of the California Code of Regulations, signed and dated within three (3) months from the date of application; or identification of a staff pharmacist pursuant to Section 5013(d) of Title 3 of the California Code of Regulations.
- (3) The full legal name and title of the individual submitting the application and either their signature and the date signed or electronic acknowledgment of submission affirming that the information provided on the application is complete, true, and accurate.
- (b) The application shall be accompanied by a non-refundable application fee of fifty dollars (\$50). The fee shall not be reduced to cover a fraction of a year.
- (c) A restricted livestock drug license is valid for the remainder of the current calendar year in which it is issued.
- (d) A restricted livestock drug licensee shall notify the Department within thirty (30) calendar days if any of the information provided pursuant to Sections 5002(a)(1) through 5002(a)(2)(E) changes after the license is issued.
- (e) A restricted livestock drug licensee shall notify the Department if any information provided pursuant to Section 5002(a)(2)(F) changes after the license is issued. This information shall be provided to the Department before a qualified individual may sell any California prescription drug as defined in Section 5007(a) of Title 3 of the California Code of Regulations.
- (f) A restricted livestock drug license application shall be denied if two or more violations have been issued to the applicant, owner(s) listed, parent company, or the location to be licensed within the previous twelve (12) months.

Note: Authority Cited: Sections 407 and 14231, Food and Agricultural Code. Reference: Sections 14322, 14323 and 14324, Food and Agricultural Code.

**§ 5003. License Renewal.**

- (a) Applications for restricted livestock drug license renewal shall be submitted between January 1 and January 31 of each year and shall be limited to the information described in Section 5002(a) of this chapter.

(b) The fee for the renewal application for a license is fifty dollars (\$50) per year, payable on or before January 31 of each year. If the fee is not paid by that date, a penalty of fifty dollars (\$50) shall be added to the fee.

(c) Any restricted livestock drug licensee that fails to renew its license on or before January 31 shall not sell restricted livestock drugs beginning February 1. Restricted livestock drugs shall not be sold by the restricted livestock drug licensee until the license has been renewed by the Department.

(d) A restricted livestock drug licensee shall notify the Department within thirty (30) calendar days if any of the information provided pursuant to Sections 5002(a)(1) through 5002(a)(2)(E) changes after the license is renewed.

(e) A restricted livestock drug licensee shall notify the Department if any information provided pursuant to Section 5002(a)(2)(F) changes after the license is renewed. This information shall be provided to the Department before a qualified individual may sell any California prescription drug as defined in Section 5007(a) of Title 3 of the California Code of Regulations.

(f) A restricted livestock drug license renewal application shall be denied if two or more violations have been issued to the applicant, owner(s) listed, parent company, or the location to be licensed within the previous twelve (12) months.

Note: Authority Cited: Sections 407 and 14231, Food and Agricultural Code. Reference: Sections 14322 and 14325, Food and Agricultural Code.

#### **ARTICLE 4. RECORDKEEPING**

##### **§ 5004. Sales Records.**

(a) Each restricted livestock drug licensee shall maintain, at the licensed location, a record of each sale of a restricted livestock drug by the licensee.

(b) The record of each sale of a restricted livestock drug shall include all of the following:

(1) The established drug name or trade name, route of administration, quantity, and lot number(s) of the restricted livestock drug sold;

(2) Date of sale;

(3) Name, address, and telephone number of the purchaser;

(4) Signature of the purchaser; and

(5) Any additional information as required under Section 5010(c)(1) of the California Code of Regulations regarding retail sales of California prescription drugs.

(c) The record of each sale of a restricted livestock drug:

(1) Shall be retained for a period of not less than three (3) years following the date of sale.

(2) Is subject to audit by the Department and shall be made available to the Department upon request.

Note: Authority Cited: Sections 407 and 14231, Food and Agricultural Code. Reference: Sections 14295, 14328, 14329 and 14330, Food and Agricultural Code.

## **ARTICLE 5. VIOLATIONS AND PENALTIES**

### **§ 5005. Violations.**

(a) It is unlawful for any business located within or outside of the State of California to make any retail sale of a restricted livestock drug within or into this state unless the business holds a valid restricted livestock drug license issued pursuant to Article 3 of Chapter 1 of Division 5 of Title 3 of the California Code of Regulations.

(b) It is unlawful for any business to fail to obtain a separate restricted livestock drug license for each place of business at which any restricted livestock drug is kept for sale, and for each mobile unit in which any such drug is kept for sale.

(c) It is unlawful for any business to sell a livestock drug that is not registered pursuant to Article 4 of Chapter 4 of Division 7 of the Food and Agricultural Code.

(d) It is unlawful for any applicant to submit inaccurate or outdated information on the restricted livestock drug license application or renewal.

(e) It is unlawful for any restricted livestock drug licensee to fail to notify the Department within thirty (30) calendar days if any of the information provided pursuant to Sections 5002(a)(1) through 5002(a)(2)(E) changes after the license is issued.

(f) It is unlawful for any restricted livestock drug licensee to sell a California prescription drug prior to providing the information required pursuant to Section 5002(a)(2)(F).

(g) It is unlawful for any restricted livestock drug licensee to fail to notify the Department prior to selling a California prescription drug if any of the information provided pursuant to Section 5002(a)(2)(F) changes after the license is issued.

(h) It is unlawful for any restricted livestock drug licensee to fail to keep sales records of restricted livestock drugs or to fail to make the required records available to the Department upon request as required by Section 5004 of this chapter.

(i) It is unlawful for any business to prevent the entry into and inspection of any premises where restricted livestock drugs are stored or sold.

(j) It is unlawful for any business to sell any restricted livestock drug that is outdated, damaged, misbranded or adulterated.

(k) It is unlawful for a restricted livestock drug licensee who does not renew their license with the Department on or before January 31 to sell any restricted livestock drugs beginning February 1 of that year.

Note: Authority Cited: Sections 407 and 14231, Food and Agricultural Code. Reference: Sections 14321, 14326, 14327, 14328, 14329, 14351, 14354, 14356, 14357, and 14362, Food and Agricultural Code.

**§ 5006. Penalties.**

(a) Upon finding a violation, the Department shall issue a notice in accordance with Section 14382 Food and Agricultural Code.

(b) A first violation of this chapter is an infraction punishable by a fine of five hundred dollars (\$500).

(c) A second or subsequent violation of this chapter is a misdemeanor punishable by a fine of one thousand dollars (\$1000).

(d) If the renewal fee is not paid by January 31, a penalty of fifty dollars (\$50) shall be added to the license fee.

Note: Authority Cited: Sections 407 and 14231, Food and Agricultural Code. Reference: Sections 14381 and 14382, Food and Agricultural Code; Sections 11445.20, 11445.30, 11445.40, 11445.50 and 11445.60, Government Code.

**TITLE 3. CALIFORNIA CODE OF REGULATIONS**  
**DIVISION 5. LIVESTOCK DRUGS**  
**CHAPTER 2. SALES OF CALIFORNIA PRESCRIPTION DRUGS**  
**SECTIONS 5007 THROUGH 5015**

**ARTICLE 1. DEFINITIONS**

**§ 5007. Definitions.**

For purposes of this chapter, the following definitions apply:

(a) "California prescription drug" means a medically important antimicrobial drug intended for use on livestock that is federally labeled for over the counter sale but requires a prescription to be sold in California pursuant to Chapter 4.5 of Division 7 of the Food and Agricultural Code.

(b) "Extra label use" means actual use or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling. This includes, but is not limited to, use in species not listed in the labeling, use for indications (disease or other conditions) not listed in the labeling, use at dosage levels, frequencies, or routes of administration other than those stated in the labeling, and deviation from the labeled withdrawal time based on these different uses.

(c) "Federal prescription drug" means a drug intended for use on livestock that is labeled with the statement: "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."

(d) "Livestock" includes all animals and poultry, including aquatic and amphibian species, that are raised, kept, or used for profit. Livestock does not include bees or those species which are usually kept as pets, such as dogs, cats, and pet birds. "Species that are raised, kept, or used for profit" means:

- (1) Livestock that are used for financial gain, commercial use, breeding, competition, or show; or
- (2) Livestock whose owners are engaged in business using animals for financial gain, commercial use, breeding, competition, or show.

(e) "Medically important antimicrobial drug" means an antimicrobial drug listed in Appendix A of the federal Food and Drug Administration's Guidance for Industry #152, including critically important, highly important, and important antimicrobial drugs, as that appendix may be amended.

(f) "Pharmacist" means a natural person to whom a license has been issued by the State Board of Pharmacy under Section 4200 of the Business and Professions Code.

(g) "Prescription" means an oral, written, or email order issued by a veterinarian that includes at least the following information:

- (1) The name and address of the livestock owner;
- (2) The name and quantity of the drug or device prescribed and the directions for use;
- (3) The date of issue;
- (4) The name, address, and telephone number of the prescribing veterinarian, and;
- (5) If in writing, the signature of the prescribing veterinarian.

(h) "Qualified individual" means a person who meets the requirements of Section 5009 of Title 3 of the California Code of Regulations.

(i) "Restricted livestock drug" means any livestock drug which is sold in such form that it might be administered to humans and if so administered would be dangerous to the health of such humans or any livestock drug which if improperly administered to livestock is dangerous to the health of such livestock or to humans who consume products from such livestock. Restricted drugs include all of the following:

- (1) Arsenic compounds and preparations;
- (2) Diethylstilbestrol and other substances which have a hormonelike action;
- (3) Sulfanilamide or substitute sulfanilamides;
- (4) Antibiotic preparations, including those medically important antimicrobial drugs federally labeled for over the counter sale listed in Appendix A of the federal Food and Drug Administration's Guidance for Industry #152, including critically important, highly important, and important antimicrobial drugs, as that appendix may be amended;
- (5) Type A Medicated Articles as defined in Section 558.3(b)(2) of Title 21 of the Code of Federal Regulations (8/24/2016), which is hereby incorporated by reference, and
- (6) Any drug that has a withdrawal period.

(j) "Restricted livestock drug licensee" is a location licensed pursuant to Article 3 of Chapter 1 of Division 5 of Title 3 of the California Code of Regulations where sales of restricted livestock drugs occur.



Note: Authority Cited: Sections 407, 14231, 14403 and 14405, Food and Agricultural Code. Reference: Sections 14203, 14321, 14400, 14403 and 14405, Food and Agricultural Code.

## **ARTICLE 2. GENERAL PROVISIONS**

### **§ 5008. Sales of California Prescription Drugs.**

(a) The provisions of this chapter apply only to restricted livestock drug licensees that choose to sell California prescription drugs pursuant to Chapter 4.5 of Division 7 of the Food and Agricultural Code. These are restricted livestock drugs under Section 14203(d) of the Food and Agricultural Code and are therefore subject to Chapter 4 of Division 7 of the Food and Agricultural Code and Chapter 1 of Division 5 of Title 3 of the California Code of Regulations, in addition to Chapter 4.5 of Division 7 of the Food and Agricultural Code and the provisions of this chapter.

(b) A restricted livestock drug licensee shall not sell any drug that is required by federal law to be sold by prescription only unless the licensee also holds a valid license under Section 4110 or 4196 of the Business and Professions Code allowing it to do so.

(c) A restricted livestock drug licensee shall only sell California prescription drugs to an end user for the sole purpose of administration to livestock. A restricted livestock drug licensee shall not sell a California prescription drug to another business for resale unless the licensee also holds a valid license under Section 4160 of the Business and Professions Code allowing it to do so.

(d) A restricted livestock drug licensee shall not sell a California prescription drug until the information required in Section 5002(a)(2)(F) of Title 3 of the California Code of Regulations has been submitted to the Department.

Note: Authority Cited: Sections 407, 14231, 14403 and 14405, Food and Agricultural Code. Reference: Sections 14203, 14262, 14281, 14321 and 14403, Food and Agricultural Code.

## **ARTICLE 3. ADDITIONAL REQUIREMENTS**

### **§ 5009. Qualified Individuals.**

(a) Each restricted livestock drug licensee that chooses to sell California prescription drugs shall identify one (1) or more employees to serve as qualified individual(s) responsible for protecting the public health and safety in the handling, storage, and sale of California prescription drugs.

(b) A qualified individual shall be at least 18 years of age.

(c) A qualified individual shall complete a training program that meets the following:

(1) Offered by one of the following:

(A) Federal, state, or local government agencies;

(B) University or college accredited by a regional or national accrediting agency recognized by the United States Department of Education; or

(C) Veterinarian technician program accredited by the American Veterinary Medical Association's Committee on Veterinary Technician Education and Activities.

(2) Addresses each of the following subjects with regard to California prescription drugs:

(A) Applicable state and federal laws, including how to identify whether a product is a California prescription drug;

(B) The importance and obligations relative to drug use on livestock, including public health threats such as residue hazards to consumers and antimicrobial resistance;

(C) How to read and understand information contained on drug labels and package inserts, including cautionary statements and withdrawal times;

(D) How to read and understand a prescription and verify that it is in accordance with the labeled use for the prescribed drug. This shall include information on terminology, abbreviations, dosages, and routes of administration for drugs prescribed by veterinarians; and

(E) How to safely store and handle California prescription drugs in accordance with the storage conditions indicated on the manufacturer's label.

(d) Alternatives to the training requirements specified in subsection (c) of this section include fulfillment of one of the following:

(1) Registration as a registered veterinary technician with the California Veterinary Medical Board;

(2) Eligibility to take the State Board of Pharmacy's pharmacist licensure examination or the California Veterinary Medical Board's veterinarian licensure examination; or

(3) Possession of a pharmacist license issued by the State Board of Pharmacy.

Note: Authority Cited: Sections 407, 14231, 14403 and 14405, Food and Agricultural Code. Reference: Section 14403, Food and Agricultural Code.

**§ 5010. Sale Requirements.**

(a) A California prescription drug shall only be sold by a qualified individual.

(b) A qualified individual shall not sell a California prescription drug without the purchaser first providing a prescription in a written, facsimile, or electronic image format. A qualified individual shall not alter or amend a prescription nor sell a California prescription drug on the basis of an oral order. Prior to selling the California prescription drug, the qualified individual shall verify:

(1) The prescription describes a use that is in accordance with the manufacturer or distributor's label for the prescribed drug; and

(2) The date sold is within the expiration date and within six months of the issuance date listed on the prescription.

(c) In addition to the recordkeeping requirements listed in Chapter 4 of Division 7 of the Food and Agricultural Code and Section 5004 of Title 3 of the California Code of Regulations, a restricted livestock drug licensee shall comply with the following provisions for each sale of a California prescription drug.

(1) Include all of the following in the record of sale:

(A) Indication that the drug sold is a California prescription drug;

(B) Identification of the qualified individual selling the drug; and

(C) A unique identification number.

(2) Retain a copy of the prescription labeled with the corresponding unique identification number listed in the record of sale.

(3) The record of sale and copy of the prescription:

(A) Shall be retained for a period of not less than three (3) years following the date of sale.

(B) Are subject to audit by the Department and shall be made available to the Department upon request.

Note: Authority Cited: Sections 407, 14231, 14403 and 14405, Food and Agricultural Code. Reference: Sections 14295, 14327, 14328, 14329, 14330, 14358, 14403 and 14405, Food and Agricultural Code.

**§ 5011. Storage and Inventory Requirements.**

(a) Each restricted livestock drug licensee shall store California prescription drugs in a secure, lockable area that shall only be accessible to the qualified individual(s) identified

to the Department pursuant to section 5002(a)(2)(F) or section 5002(e) of Title 3 of the California Code of Regulations.

(b) Each restricted livestock drug licensee shall maintain on the premises fixtures and equipment in a clean and orderly condition. California prescription drugs shall be stored in accordance with the storage conditions indicated on the manufacturer's label.

(c) No restricted livestock drug licensee shall sell a California prescription drug except in the container in which it is packaged by the manufacturer or distributor.

(1) A restricted livestock drug licensee may break down case lots of California prescription drugs, so long as the seals on the individual containers are not broken.

(2) A restricted livestock drug licensee shall not open an individual container and count out or measure out any quantity of California prescription drugs.

(d) Each restricted livestock drug licensee shall adhere to the following procedures for handling damaged or outdated California prescription drugs:

(1) California prescription drugs that are outdated, damaged, misbranded or adulterated shall be placed in a quarantine area and physically separated from other drugs until they are disposed of in the manner indicated in the written procedures developed in accordance with Section 5012.

(2) Any California prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be placed in a quarantine area and physically separated from other drugs until they are disposed of in the manner indicated in the written procedures developed in accordance with Section 5012.

(e) Each restricted livestock drug licensee shall maintain an inventory of California prescription drugs, shall verify that inventory records are free from errors and inaccuracies, and shall identify and record losses or thefts of California prescription drugs.

(f) All records related to the receipt, storage, inventory, sale, and disposition of California prescription drugs:

(1) Shall be retained for a period of not less than three (3) years from the date of creation.

(2) Are subject to audit by the Department and shall be made available to the Department upon request.

Note: Authority Cited: Sections 407, 14231, 14403 and 14405, Food and Agricultural Code. Reference: Sections 14295, 14327, 14330, 14358 and 14403, Food and Agricultural Code.

**§ 5012. Written Operating Procedures.**

(a) Each restricted livestock drug licensee shall establish, maintain, and adhere to store-specific written operating procedures for the receipt, storage, inventory, sale, and disposition of California prescription drugs.

(b) Each qualified individual employed by a restricted livestock drug licensee shall receive training on the licensee's store-specific written operating procedures.

(c) All records pertaining to this section:

(1) Shall be retained for a period of not less than three (3) years from the date of creation.

(2) Are subject to audit by the Department and shall be made available to the Department upon request.

Note: Authority Cited: Sections 407, 14231, 14403 and 14405, Food and Agricultural Code. Reference: Sections 14295, 14327, 14330, 14403 and 14405, Food and Agricultural Code.

**§ 5013. Pharmacist Oversight.**

(a) Each restricted livestock drug licensee shall either retain a consulting pharmacist or employ a pharmacist on staff.

(b) If a restricted livestock drug licensee chooses to retain a consulting pharmacist, the consulting pharmacist shall complete the following on a quarterly basis:

(1) Review, approve, and revise the restricted livestock drug licensee's store-specific written operating procedures as defined in Section 5012(a) of this chapter.

(2) Ensure the restricted livestock drug licensee is following all written procedures and is maintaining all records required pursuant to Sections 5004 and 5011(f).

(3) Issue a signed, written certification stating whether or not the restricted livestock drug licensee is operating in compliance with California law and regulations regarding California prescription drugs.

(c) The consulting pharmacist shall notify the Department within ten (10) days if the restricted livestock drug licensee is not in compliance with California law and regulations regarding California prescription drugs.

(d) If a restricted livestock drug licensee chooses to employ a pharmacist on staff, the staff pharmacist shall:

(1) Review, approve, and revise the restricted livestock drug licensee's store-specific written operating procedures as defined in Section 5012(a) of this chapter.

(2) Ensure the restricted livestock drug licensee is following all written procedures and is maintaining all records required pursuant to Sections 5004 and 5011(f).

(3) A pharmacist employed by a restricted livestock drug licensee shall be exempt from the following provisions of this chapter:

(A) Prohibition on the sale of a California prescription drug on the basis of an oral order as specified in Section 5010(b).

(B) Prohibition on the sale of a California prescription drug for an extralabel use as specified in Section 5010(b)(1).

(e) The restricted livestock drug licensee shall disclose to the Department if the consulting or staff pharmacist has an ownership or financial interest in the location.

(f) All records pertaining to this section:

(1) Shall be retained for a period of not less than three (3) years from the date of creation.

(2) Are subject to audit by the Department and shall be made available to the Department upon request.

Note: Authority Cited: Sections 407, 14231, 14403 and 14405, Food and Agricultural Code. Reference: Sections 14295, 14327, 14330, 14403 and 14405, Food and Agricultural Code.

#### **ARTICLE 4. VIOLATIONS AND PENALTIES**

##### **§ 5014. Violations.**

(a) It is unlawful for any restricted livestock drug licensee to sell any drug that is required by federal law to be sold on prescription only unless the licensee also holds a valid license under Article 7 or Article 15 of Chapter 9 of Division 2 of the Business and Professions Code allowing them to do so.

(b) It is unlawful for any restricted livestock drug licensee to sell any California prescription drug to another business for resale unless the licensee also holds a valid license under Article 11 of Chapter 9 of Division 2 of the Business and Professions Code allowing them to do so.

(c) It is unlawful for any employee of a restricted livestock drug licensee to sell a California prescription drug unless they are a qualified individual that meets the

requirements of Section 5009 of this chapter that has been identified to the Department at the time of licensure, renewal, or upon appointment.

(d) It is unlawful for any qualified individual to sell any California prescription drug at retail unless the purchaser provides a valid prescription issued by a veterinarian.

(e) It is unlawful for any qualified individual to alter or amend any prescription.

(f) It is unlawful for any qualified individual who is not a licensed pharmacist to sell any California prescription drug on the basis of an oral order.

(g) It is unlawful for any qualified individual who is not a licensed pharmacist to sell any California prescription drug for a purpose that is not in accordance with its manufacturer or distributor's label.

(h) It is unlawful for any qualified individual to sell any California prescription drug at retail beyond the expiration date listed on the prescription or if the date of issuance of the prescription is more than six months prior to the date of purchase.

(i) It is unlawful for any restricted livestock drug licensee to fail to keep sales records of California prescription drugs or to fail to make the required records available to the Department upon request as required by Section 5010 of this chapter.

(j) It is unlawful for any restricted livestock drug licensee to fail to comply with the minimum standards for receipt, storage, inventory, sale, and disposition of California prescription drugs as required by Section 5011 of this chapter.

(k) It is unlawful for any qualified individual to sell any California prescription drug except in the container in which it is packaged by the manufacturer or distributor.

(l) It is unlawful for any qualified individual to sell any California prescription drug that is outdated, damaged, misbranded or adulterated.

(m) It is unlawful for any restricted livestock drug licensee to fail to comply with the minimum standards for written operating procedures for sales of California prescription drugs as required by Section 5012 of this chapter.

(n) It is unlawful for any restricted livestock drug licensee to sell California prescription drugs without either retaining a consulting pharmacist or employing a pharmacist on staff as required by Section 5013 of this chapter.

(o) It is unlawful for any business to prevent the entry into and inspection of any premises where California prescription drugs are stored or sold.

Authority Cited: Sections 407, 14231, 14403 and 14405, Food and Agricultural Code.  
Reference: Sections 14203, 14262, 14281, 14295, 14321, 14327, 14328, 14329, 14330, 14358, 14403 and 14405 Food and Agricultural Code.

**§ 5015. Penalties.**

(a) Upon finding a violation, the Department shall issue a notice in accordance with Section 14408 Food and Agricultural Code.

(b) A person who violates this chapter shall be liable for a civil penalty of two hundred and fifty dollars (\$250) for each day a violation occurs.

(c) For a second or subsequent violation, a person who violates this chapter shall be punishable by an administrative fine, levied by the Secretary, in the amount of five hundred dollars (\$500) for each day a violation occurs.

Note: Authority Cited: Sections 407, 14231, 14403 and 14405, Food and Agricultural Code. Reference: Sections 14382 and 14408, Food and Agricultural Code; Sections 11445.10, 11445.20, 11445.30, 11445.40, 11445.50 and 11445.60, Government Code.